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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,791	11/12/2003	Christopher William Aston	AM101119	8289
25291	7590	06/14/2006	EXAMINER	
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			LU, FRANK WEI MIN	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/706,791	Applicant(s) ASTON ET AL.	
	Examiner Frank W. Lu	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 and 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/03, 1/04, and 8</u> . | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group IV, claims 23-27 in the reply filed on June 2, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

2. The disclosure is objected to because of the following informalities: (1) there are several protein sequences in Figure 9. However, there are no sequence ID Nos in BRIEF DESCRIPTION OF THE DRAWINGS of the specification; and (2) there are Figures 9A to 9C. However, BRIEF DESCRIPTION OF THE DRAWINGS only describes Figure 9.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Enablement

Claims 23-27 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance in the specification to show that a composition which dissociates a protein complex comprising an Insulin-like growth factor (IGF) and an Insulin-like growth factor binding protein (IGFBP) can be used as a pharmaceutical composition. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether a composition which dissociates a protein complex comprising an Insulin-like growth factor (IGF) and an Insulin-like growth factor binding protein (IGFBP) can be used as a pharmaceutical composition.

The invention is directed to a pharmaceutical composition which dissociates a protein complex comprising an Insulin-like growth factor (IGF) and an Insulin-like growth factor binding protein (IGFBP). A pharmaceutical composition is read as a composition used for the purpose of treating a disease. However, the specification does not show that a composition which dissociates a protein complex comprising an Insulin-like growth factor (IGF) and an

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Insulin-like growth factor binding protein (IGFBP) can be used for treating any kind of disease. In view of claims 23-27, it is unclear how a composition which dissociates a protein complex comprising an Insulin-like growth factor (IGF) and an Insulin-like growth factor binding protein (IGFBP) can serve as a pharmaceutical composition.

With above unpredictable factor, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. The undue experimentation at least includes to test whether a composition which dissociates a protein complex comprising an Insulin-like growth factor (IGF) and an Insulin-like growth factor binding protein (IGFBP) can be used for treating any kind of disease so that such composition can serve as a pharmaceutical composition.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 23-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Sakano *et al.*, (US Patent No. 6,428,781 B1, priority date: December 26, 1997).

Regarding claims 23-27, Sakano *et al.*, teach a pharmaceutical composition (ie., [Leu27, Leu43]rIGF-II or anti-IGFBP antibodies) which dissociates a protein complex comprising an Insulin-like growth factor (IGF) and an Insulin-like growth factor binding protein (IGFBP) as

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recited in claim 23 wherein the protein complex is further defined as a dimeric complex comprising IGF and IGFBP (ie., a complex formed by IGF and IGFBP) as recited in claim 24 or the protein complex further comprises an acid labile subunit (ALS) and the ratio of IGF to IGFBP to ALS is 1:1:1 (ie., a ternary complex formed by IGF, IGFBP, and ALS) as recited in claim 25, the composition is a small molecule (ie., [Leu27, Leu43]rIGF-II or one of anti-IGFBP antibodies) as recited in claim 26, and the composition is a peptide (ie., [Leu27, Leu43]rIGF-II or one of anti-IGFBP antibodies) as recited in claim 27 (see columns 9 and 10, Examples 16 and 17 in columns 21, and Figures 16 and 17).

Therefore, Sakano *et al.*, teach all limitations recited in claims 23-27.

Conclusion

7. No claim is allowed.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

June 12, 2006

A handwritten signature in black ink, appearing to read 'Frank Lu', written in a cursive style.

FRANK LU
PRIMARY EXAMINER